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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,592	03/01/2004	Israel R. Charo	02307K-085042US	3201

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EXAMINER	
LYLES, JOHNALYN D	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/791,592	CHARO ET AL.	
	Examiner	Art Unit	
	Johnalyn Lyles	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-5 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-5 and 9-12* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed on 3/1/2005 has been received and entered.

2. Prosecution on the merits of this application is reopened on claims 1-5 and 9-12 considered unpatentable for the reasons indicated below: new prior art rejections.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 112 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

This application repeats a substantial portion of prior Application No. 09/625,573, filed 7/25/2000, Application No. 08/446,669, filed 5/25/1995, and Application No. 08/182,962, filed 01/13/1994, and adds new claims and additional disclosure not presented in the prior applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the

prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

The priority date of the instant application is 1 March 2004.

Withdrawn Objections and/or Rejections

Specification and Claim Objections

The objection to the Drawings as set forth at pp. 2-3, paragraph 5 of the previous Office Action (2/4/05) is herby withdrawn in view of Applicant's amendments (3/1/05).

The objection to the Specification as set forth at pp. 3, paragraph 6 of the previous Office Action (2/4/05) is herby withdrawn in view of Applicant's amendments (3/1/05).

New Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The following recitations are not supported within the specification and priority documents. As a Continuation, the instant application must have support for the subject matter in the parent applications. No support in the parent applications (Application Nos.: 09/625,573, 08/446,669, and 08/182,962) can be found for the following limitations recited in the claims [see MPEP §608.04(a)]:

a. claim 1, "binding fragment thereof"

b. claim 2, "detectable label"

c. claim 3, "radioactive isotope"

d. claim 4, "monoclonal antibody"

e. claim 5, "humanized antibody"

f. claim 9, "A method of making . . ."

g. claim 10, "A composition . . ."

h. claim 11, ". . . neutralization of activity of the MCP-1 receptor polypeptide"

i. claim12, "An antibody made by the method of claim 9"

The presentation of the above subject mater in the original claims of the instant Application constitutes the introduction of **New Matter**. This is not permitted in the filing of a Continuation under 35 U.S.C. 120 [see MPEP §201.07 and 201.08].

Claims 1-5 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **written description** requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are drawn to an antibody or "binding fragment," which specifically binds MCP-1 receptor polypeptide which encompasses a wide variety of antigen.binding fragments. Further, claim 11 is drawn to an antibody or binding fragment, wherein specific binding results in the "neutralization of activity" of the MCP-1 receptor polypeptide. The instant disclosure of the antibody, which specifically binds MCP-1 receptor polypeptide, does not adequately describe the scope of the use of "binding fragment thereof" or wherein said binding "results in neutralization of activity."

A description of a genus may be achieved by means of a recitation of a representative number of species, defined by a specific structure and/or function, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. A genus claim may be supported by a representative number of species as set forth in Regents of the University of California v Eli Lilly & Co, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997), which states:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention". Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1980) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which

> makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d 1565, 1572, 41 USPQ2d at 1966.

The instant specification fails to provide sufficient descriptive information, such as definitive structural and functional features of the binding fragments and/or wherein said binding results in neutralization of activity. There is no description of the conserved regions, which are critical to the structure and function of the genus claimed. Structural features that could distinguish the binding fragment in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to identify the binding fragment encompassed. No identifying characteristic or property of "binding fragment" and/or wherein such results in neutralization of activity are provided such that one of skill would be able to predictably identify the encompassed fragments as being identical to those instantly claimed.

Vas-cath Inc. v. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-cath, page 1116).

Claims 1 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the **enablement** requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is insufficient to enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors relevant to this discussion include the quantity of experimentation necessary, the lack of working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims.

Applicant's claims are directed to binding fragments, which specifically bind MCP-1 receptor polypeptide and/or wherein binding results in neutralization of activity. The specification does not enable the broad scope of the claims, which encompasses a multitude of antigen binding fragments and/or neutralization of activity because the specification does not teach which fragments can be used such that requisite functionality is maintained. The specification provides essentially no guidance as to which of the essentially infinite possible choices is likely to be successful in any particular use, including neutralization of activity. Thus, applicants have not provided sufficient guidance to enable one skilled in the art to make and use the claimed derivatives in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made and still maintain activity/utility is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986). Thus, the skilled

artisan cannot readily make and use the claimed binding fragments without further undue experimentation.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et. al., US Patent No. 6723520, filed 1/03/2002, issued 4/20/2004.

The reference teaches an antigen binding fragment from an antibody which binds to a mature monocyte/dendritic cell receptor for chemokine (M/DC CR), which is SEQ ID NO: 2 of the instant application (see alignment) and methods of generating an antigen-binding compound complex and a cell which makes the antibody. The binding compound is one wherein the polypeptide is a mouse or human protein; the antibody is raised against a mature peptide sequence; the binding compound is detectably labeled; the antibody is a monoclonal antibody; and the binding compound is in a sterile composition (see pg 2, ¶ 0012-3 and claims 14-15 and 18).

The reference teaches neutralizing antibodies against a specific chemokine embodiment and soluble fragments of the chemokine, which contain a high affinity receptor binding site, can be used to inhibit chemokine activity in tissues, e.g., tissues experiencing abnormal physiology (see pg 12, ¶ 0093).

The reference also teaches preparing monoclonal antibodies from various mammalian hosts, such as mice, rodents, primates, humans, etc. The methods involve injecting an animal with an immunogen, then the animal is then sacrificed and cells

taken, e.g., from its spleen, which are then fused with myeloma cells. The resulting hybrid cell or "hybridoma" is capable of reproducing in vitro. The population of hybridomas is then screened to isolate individual clones, each of which secrete a single antibody species to the immunogen. In this manner, the individual antibody species obtained are the products of immortalized and cloned single B cells from the immune animal generated in response to a specific site recognized on the immunogenic substance. Large amounts of antibody may be derived from ascites fluid from an animal (see pg 14, ¶ 0120).

The reference teaches the polypeptides and antibodies may be used with or without modification, including chimeric or humanized antibodies. Further, the polypeptides and antibodies will be labeled with a detectable signal such as radionuclides, enzymes, substrates, cofactors, inhibitors, fluorescent moieties, chemiluminescent moieties, magnetic particles, and the like (see pg 14, ¶ 0121).

Thus, the reference meets all the limitations of the claims as noted above.

Suggestion for amendment to possible allowable subject matter

The following claim 13 drafted by the examiner and considered to distinguish patentably over the art of record in this application, is presented to applicant for consideration:

Claims 1-12 (cancelled)

Claim 13 (new) An antibody, which specifically binds MCP-1 receptor polypeptide, wherein the polypeptide comprises the amino acid sequence of SEQ ID NO: 2.

Support for the suggested claims can be found:

a. Instant Application ([0009], [0017], [0086], in the claims as originally filed.

b. Application No. 09/625,573, on pp. 4, lines 11-15; pp. 8, lines 21-25; and pp. 27, lines 4-11.

c. Application No. 08/446,669, on pp. 4, lines 11-15; pp. 8, lines 21-25; and pp. 27, lines 4-11.

d. Application No. 08/182,962, on pp. 5, lines 1-15; pp. 9, lines 1-17; and pp. 26, lines 11-17 and Figure 2.

Conclusion

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnalyn Lyles whose telephone number is 571-272-3433. The examiner can normally be reached on M-F 8 am - 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

jdl

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6-8-05